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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,295	11/14/2000	Vicky L. Funanage	2019659-0139	6833

7590 05/17/2004
McGuire Woods
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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,295

Applicant(s)

FUNANAGE ET AL.

Examiner

Eileen O'Hara

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,11-14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,11-14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-3, 5-9, 11-14 and 16 are pending in the instant application. Claims 1, 5, 6, 8, 9, 11, 13, 14 and 16 have been amended and claims 4, 10 and 15 have been canceled as requested by Applicant in the Paper filed March 1, 2004.

Withdrawn Rejections

- 2.1 The rejection of claims under 35 USC 112 § 2 is withdrawn in view of Applicants' amendment.
- 2.2 The provisional rejection under obviousness-type double patenting over claim 34 of copending Application No. 10/286,947 is withdrawn.

Maintained Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1-3, 5-9, 11-14 and 16 remain rejected under the judicially created doctrine of obviousness-type double patenting over claims 2-11 of U.S. Patent No. 6,475,984, for reasons of record in the previous office action, Paper No. 11262003, and below.

Applicants' arguments on pages 6-7 of the response that the requirements for a rejection under the judicially created doctrine of obviousness-type double patenting are similar to the requirements for establishing a *prima facie* case of obviousness under 35 USC § 103, and that three basic criteria must be met, have been fully considered but are not deemed persuasive. Although the '984 patent does not teach or suggest that lung surfactant production in an individual can be improved by administration of leptin, many of the individuals being treated in the current claims (individual with impaired lung surfactant production, respiratory distress syndrome or bronchial dysplasia) are the same patient population (be small-for-gestational age or premature infants) as in the claims of the '984 patent. It is well-known in the art that insufficient surfactant production is one of the most common problems associated with premature or small-for-gestational age infants. Accordingly, a significant proportion of the population treated by the method of the patent would inherently benefit from the increased surfactant production resulting from administration of leptin. There is no requirement for a reasonable expectation of success or for a particular finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with the knowledge to modify the claimed invention, because it is the same patient population that is being treated with the same compound, and administration of leptin would enhance growth as well as improve lung surfactant production in the same patient.

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Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 6,475,984 in view of Pellemounter et al., Science, Vol. 269. No. 5223, 1995, pages 540-543, for reasons of record in the previous office action, Paper No. 11262003, and below.

Applicants' arguments on pages 7-8 of the response that Pellemounter is directed to the effect of the OB protein on metabolism and appetite and does not teach or suggest the leptin would improve lung surfactant production, and is not adequate as a second reference have been fully considered but are not deemed persuasive. Pellemounter is cited because of the disclosure of recombinantly produced leptin – it is the '984 patent that teaches the treatment of the same individuals with leptin as those in the currently pending claims, and it would be obvious to enhance growth by addition of of recombinantly produced leptin. Therefore, the rejections are maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

4. No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in black ink, appearing to read "Lorraine Spector", with a large, stylized initial "L".

LORRAINE SPECTOR
PRIMARY EXAMINER